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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,237	07/19/2001	Jeffrey B. Miller	08472-720003 / MGH-1176.2	9307
26161	7590	12/01/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/909,237

**Applicant(s)**

MILLER, JEFFREY B.

**Examiner**

Maria B Marvich, PhD

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-31 and 34-54 is/are pending in the application.
- 4a) Of the above claim(s) 21-24, 37, 38, 40-49, 51, 52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-27, 29-31 and 34-36 is/are rejected.
- 7) ☒ Claim(s) 28, 50 and 53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This office action is in response to an amendment filed 9/10/04. Claims 1-20 and 32-33 have been cancelled. Claims 21-31 and 34-54 are pending in this application. Claims 25, 27, 34-36, 39 and 53 have been amended. Claim 39 has been amended to depend from claim 38, which has been withdrawn. Therefore, claim 39 is withdrawn as directed to non-elected subject matter. Claims 21-24, 37-49, 51, 52 and 54 have been withdrawn. Therefore, claims 25-31, 34-36, 50 and 53 are under examination in this office action.

### ***Response to Amendment***

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by applicant's amendment and therefore, this action is non-final.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25 and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al (US 2004/0006018 A1; see entire document) as evidenced by Chen and Goldhamer

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(Reproductive Biology and Endocrinology 2003, Vol 1(101) pages 1-7; see entire document).

**This is a new rejection.**

Baker et al teach the stimulation of satellite cells and their subsequent development into myoblasts by the addition of CT-1. The human myoblasts are then used in therapeutic methods (see e.g. paragraph 306). Chen and Goldhamer teach that satellite cells are myogenic stem cells (see e.g. abstract).

Claims 25 and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Austin et al (US 5,435,999; see entire document) as evidenced by Chen and Goldhamer (Reproductive Biology and Endocrinology 2003, Vol 1(101) pages 1-7; see entire document). **This is a new rejection.**

Austin et al teach the stimulation of satellite cells and their subsequent development into myoblasts by the addition of LIF. Human stem cells are used (see e.g. paragraph col 2, line 37-42). Chen and Goldhamer teach that satellite cells are myogenic stem cells (see e.g. abstract).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-27, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (US 2004/0006018 A1; see entire document) or Austin et al (US 5,435,999; see entire

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document) in view of Cantini et al (In Vitro Cell Dev Biol Anim, 1994, Vol 30A, pages 131-133; see entire document). **This is a new rejection.**

Applicants claim an isolated human muscle stem cell that comprises an exogenous nucleic acid sequence.

The teachings of Baker et al or Austin et al are described above and are applied as before except:

Neither Baker et al nor Austin et al teach that the human muscle stem cells comprise exogenous nucleic acid.

Cantini et al teach delivering exogenous genes in tissue-specific for expression of exogenous genes in re-implanted muscle cells to cure inherited muscle diseases such as DMD (see e.g. Cantini et al, page 131, col 1, paragraph 1). To demonstrate the effectiveness of gene transfer into satellite cells, vectors comprising beta-galactosidase ( $\beta$ -gal), a marker protein for transfection, were introduced into the cells (see e.g. abstract). The expression of  $\beta$ -gal functions as a good indication that the promoter driving expression is muscle stem cell active. The promoter, while a CMV promoter, is active in the satellite cells given the expression of  $\beta$ -gal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to transform the human muscle stem cells taught by Baker et al or Austin et al with the method of transformation taught by Cantini et al because Baker et al and Austin et al teach that it is within the ordinary skill of the art to grow human muscle stem cells *in vitro* and because Cantini et al teach that it is within the ordinary skill of the art to express exogenous genes in cultured muscle stem cells. One would have been motivated to do so in order to receive the expected benefit of delivering exogenous genes so that satellite cells can function as a somatic

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tissue for the introduction of foreign genes into adult muscle to treat inherited disease such as DMD (see e.g. Cantini et al, page 131, col 1, paragraph 1). Austin et al and Baker et al contemplate treatment of DMD by injection of satellite cells (Austin et al, col 3, line 25-41 and Baker et al paragraph 0306). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

Claims 25-27, 29-31 and 34-36 are rejected.

Claims 28, 50 and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

April 29, 2004

  
GERRY LEFFERS  
PRIMARY EXAMINER